

REMARKS

Applicants did not amend or add any claims. Claims 1 to 6 and 8 are pending. Claims 1 to 6 are under consideration.

Drawings

The Examiner required new formal drawings. Action at page 2 to 3. Applicants submit herewith a Submission of Formal Drawings with formal Figures 1 to 8o. The margins, format, and text of those figures meet the requirements of 37 C.F.R. § 1.84. The formal Figures do not add new matter.

Specification

The Examiner objected to the disclosure because of informalities. Action at page 3. The Examiner required amendment of the descriptions of Figures 7 and 8 and renumbering of the 8 consecutive drawings of Figure 8. Id.

Applicants amended the specification such that the descriptions of Figures 7 and 8, respectively, include the headings 7A-C and 8a to 8o. Applicants respectfully request that the Examiner withdraw the objections concerning the figures.

The Examiner also required correction of the address of the American Type Culture Collection ("ATCC"). Action at page 3. Applicants amended the specification to correct the address of the ATCC.

The Examiner contended that the "application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825," because the application does not contain a copy of a Sequence Listing in either paper copy or computer readable form. Action at page 3. The Examiner also noted that "[s]equences appear in Figure 6 without sequence identifiers." Id.

Applicants submit the Submission of Sequence Listing, which includes the requested computer readable form sequence listing, a paper copy, and a statement under 37 CFR § 1.821(f). In addition, Applicants submit the request for Approval of Drawing Change, which requests approval to amend Figure 6 to add SEQ ID NOs to each recitation of a nucleotide or polypeptide sequence in the figure. Applicants respectfully assert that the application now complies with the requirements of 37 CFR §§ 1.821 to 1.825.

Double Patenting

The Examiner provisionally rejected claims 1 to 6 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1 to 5 and 19 of copending Application No. 08/728,963. Action at page 4. The Examiner contended that “[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a library of cultured eukaryotic cells with vectors integrated into a cellular transcript.” Id. at pages 4 to 5.

Since the rejections are provisional, Applicants respectfully request that they be held in abeyance until claims of either case are otherwise allowable. At that time, the claims in question can be considered to determine whether a terminal disclaimer may be appropriate.

The Examiner provisionally rejected claims 1 to 6 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1 to 6 and 28 of copending Application No. 09/570,923. Action at page 5. The Examiner contended that “[a]lthough the conflicting claims are not identical, they are not

patentably distinct from each other because the instant claims are drawn to a library of cultured eukaryotic cells with vectors integrated into a cellular transcript.” *Id.* at page 5.

Since the rejections are provisional, Applicants respectfully request that they be held in abeyance until claims of either case are otherwise allowable. At that time, the claims in question can be considered to determine whether a terminal disclaimer may be appropriate.

Rejections Under 35 U.S.C. § 102

The Examiner rejected claims 1 and 2 under 35 U.S.C. § 102(a) as allegedly being anticipated by Gruber et al. Action at page 6.

Applicants traverse the rejection. The Examiner bears the burden of establishing a *prima facie* case of anticipation. *In re Mullin*, 481 F.2d 1333, 1336 (CCPA 1973). The Examiner must conduct an anticipation analysis on a limitation by limitation basis, and must show that **every** limitation of the claim was identically shown in the single reference. *Gechter v. Davidson*, 43 U.S.P.Q.2d 1030, 1035 (Fed. Cir. 1997) (emphasis added). Conclusory findings are entirely inadequate. *Id.* at page 1034.

Here, the Examiner only proffered a bare conclusion that Gruber et al. teaches “a library of cultured eukaryotic cells transfected with vectors which are stably integrated internally to a cellular transcript, and 5' to a cellular transcript.” Action at page 6.

The process recited in claim 1, however, comprises treating a first group of cells to stably integrate a first vector; treating a second group of cells to stably integrate a second vector; and selecting certain cells. The Examiner has not even attempted to establish that Gruber et al. teaches all of the limitations in the claimed process. For example, the Examiner failed to establish, or even assert, that Gruber et al. teaches a process that includes treating a second group of cells to stably integrate a second

vector. Thus, the analysis by the Examiner is insufficient to establish a *prima facie* case of anticipation.

Applicants respectfully request that the Examiner reconsider and withdraw the § 102(a) rejections in view of Gruber et al. If the Examiner maintains those rejections, Applicants request that the Examiner point out with particularity where Gruber et al. teaches all of the limitations of each of the rejected claims.

The Examiner rejected claims 1 to 6 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,679,523 ('523 patent). Action at page 6.

Again, the Examiner failed to properly establish a *prima facie* case of anticipation. The Examiner only provided the bare conclusion that the '523 patent teaches "a library of cultured eukaryotic cells transfected, infected or retrotransfected with vectors which are stably integrated internally to a cellular transcript, and 5' to a cellular transcript in a mammal." Action at page 6. Those mere conclusory findings do not provide sufficient basis for a *prima facie* case of anticipation. For example, the Examiner failed to establish, or even assert, that the process taught in Gruber et al. includes treating a second group of cells to stably integrate a second vector.

Thus, Applicants respectfully request that the Examiner reconsider and withdraw the § 102(e) rejections in view of the '523 patent. If the Examiner maintains those rejections, Applicants request that the Examiner point out with particularity where the '523 patent teaches all of the limitations of each of the rejected claims.

Applicant respectfully asserts that the present application is in condition for allowance and requests that the Examiner issue a timely Notice of Allowance. If the Examiner does not consider the application to be allowable, the undersigned requests

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that, prior to taking action, the Examiner call him at (650) 849-6614 to set up an interview.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
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By: Bart W. Wise
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APPENDIX - MARKED-UP COPY OF AMENDMENTS

Replacement paragraphs for the paragraphs beginning on page 8, line 31, and ending on page 9, line 1:

Figures 7A-C. Provide[s] a diagrammatic representation of VICTRs 3 and 20 as well as the transcripts that result after integration into a hypothetical region of the target cell genome (*i.e.*, "Wildtype" Locus).

Figures 8a-o. Provide[s] a representative list of a portion of the known genes that have been identified using the disclosed methods and technology.

Replacement paragraph for the paragraph beginning on page 39, line 35, and ending on page 40, line 8:

The following plasmids have been deposited at the American Type Culture Collection (ATCC), Manassas, Virginia, [Rockville, MD,] USA, under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure and Regulations thereunder (Budapest Treaty) and are thus maintained and made available according to the terms of the Budapest Treaty. Availability of such plasmids is not to be construed as a license to practice the invention in contravention of the rights granted under the authority of any government in accordance with its patent laws.

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